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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,159	04/25/2001	Yin Luo	RIGL-010CIP2	8575

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EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,159	LUO ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-30 and 38-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30 and 38-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 27-30 and 37-43 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 9-16-03, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

Examiner has noted that the applications related to the instant application as recited in the first line of the specification have matured into US patents. Applicants are urged to update the relationship information response to this Office action.

Sequence Compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that applicants fail to provide a SEQ ID NO for sequence depicted on page 14. See particularly 37 CFR 1.821(d).

Claim Objections

Claim 27 is objected to because of the following informalities: Claim 27 recites redundant phrases. For example the phrase "wherein said TaHo protein is encoded by a nucleic acid having at least 90% identity to the nucleic acid ....". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-30, 38-43 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Claims 27-30, 38-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying agents which modulate the activity of a polypeptide with PARP activity in the presence of chromatin (DNA), histones and Mg2+, does not reasonably provide enablement for such a method which does not involve the inclusion of chromatin (DNA), histones and Mg2+ in the above assay. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to. Prior art teaches that the presence of DNA and histones as absolute requirement for the reaction of this enzyme. Such a requirement critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Factors to be considered in determining whether undue experimentation is required, are summarized in *In* re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

A review of the scientific literature shows that PARP requires the presence of DNA, histones and Mg2+ for NAD hydrolyzing activity (see enclosed references). However, the specification and the claims are silent regarding this essential step in the reaction. It would require undue experimentation of the skilled artisan to make and use the claimed method as written.

The specification does not support the enablement of the claims because the specification does not establish: (A) the absolute requirement of DNA, histones and Mg2+ in the reaction mixture for the NAD hydrolyzing activity that has been well recorded in the art. and (B) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of agents capable of modulating the PARP activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-30, 38, 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Koide et al. (Biochemical Soc. Transactions, 1973, Vol. 1(3):644-648) or Kristensen et al. (Eur. J. Biochem., 1976, Vol. 70(2):441-446), Tsopanakis et al. (Eur. J. Biochem., 1978, Vol. 90(2):337-345). This rejection is based upon the public availability of a printed publication. Claims 27-30, 38, 41-43 of the instant application is drawn to a method of screening for a bioactive agent capable of modulating PARP activity comprising contacting the candidate compound with a polypeptide having PARP activity wherein said polypeptide is encoded by polynucleotide having at least 90% sequence identity with SEQ ID NO:1 or 2 and has at least 95% identity with SEQ ID NO:3 or 4, wherein the bioactive compound is a small molecule and wherein source of poly ADP-ribose is NAD which is radioactively labeled or biotinylated. Koide et al. or Kristensen et al. or Tsopanakis et al. disclose the isolation and purification of polypeptides with PARP activity from several sources and also disclose assays for determining the activity of the enzyme as well as identify agents which modulate the activity of said PARP polypeptide. The references disclose that agents such as DTT, or NAD itself modulated the activity of the enzyme. Thus Koide et al. or Kristensen et al. or Tsopanakis et al. anticipate claim 1 of this application as written. Applicants may argue that the above references do not teach all the limitations of the claims such as the sequences of polynucleotides and the polypeptides. However, Examiner takes the position that such characteristics of a polypeptide are inherent characteristics. Polypeptides are indeed encoded by polynucleotides and therefore, Examiner takes the position that the polypeptides in the references are inherently encoded by polynucleotides that are 90% identical

SEQ ID NO:1 or 2 or 90% identical to SEQ ID NO:1 or 2 and inherently have an amino acid sequence that is either SEQ ID NO:3 or 4 or that is at least 95% identical to SEQ ID NO:3 or 4. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-30, 38-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No.6,589,725. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the

reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 27-30, 38-43 of the instant application and claims 1-7 of the reference patent are both directed to methods of identifying agents capable of modulating the activity of tankyrase polypeptide.

While an *in vitro* cell free method appears to be claimed in the instant invention in the instant application the reference patent claims are directed to method comprising a cell expressing PARP polypeptide. The portion of the specification (and the claims) in the reference patent that supports the recited method includes several embodiments that would anticipate the method claimed in claims 27-30, 38-43 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims 1-7 of the reference patent when there is specifically recited embodiment that would either anticipate or render obvious mainly claims 27-30, 38-43 of the instant application. Alternatively, claims 27-30, 38-43 cannot be considered patentably distinct over claims 1-7 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-7 of that patent and falls within the scope of claims 27-30, 38-43 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-7 of the reference by selecting a specifically disclosed embodiment that supports those claims i.e., an vitro cell free method of determining agents that modulate the PARP activity. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-7 of the reference patent.

Conclusion

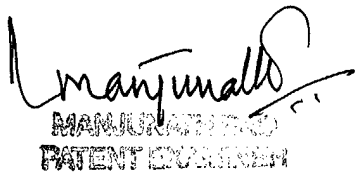
None of the claims are allowable.

Examiner has withdrawn the previous scope of enablement rejection and the written description rejection based on the arguments provided by the applicant. Examiner has also withdrawn the rejection of claim under 102(e) based on the 37 CFR Rule 1.131 declaration by the applicant. However, new rejections are in place now due to the availability of references at this time during the prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao
December 4, 2003